K072444

510(K) SUMMARY

APR - 4 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: **GWOWEI Technology CO., LTD.**

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Contact: Mr. Wilson Yeh / Manager

2. Device Name :

Trade Name: **WELLGRAFT PE I Resorbable Bone Void Filler**

Common Name: **Bone Void Filler**

Classification name filler, bone void, calcium compound

3. DEVICE CLASS **WELLGRAFT PE I Resorbable Bone Void Filler** have been classified as

Regulatory Class: II

Product Code: MQV

Panel : Orthopedic

Regulation Number: 21CFR 888.3045

4. Predicate Device: The predicate device is the

- **OSTEO-G BONE VOID FILLER SYSTEM (K031319)** marketed by **ASPINE USA, INC.**

5. Device Description: The **WELLGRAFT PE I Resorbable Bone Void Filler** consists of high purity grade calcium sulfate hemihydrate powder and mixing solution. When mixed according to the directions, WELLGRAFT PE I Resorbable Bone Void Filler **forms** the biodegradable, biocompatible and rediopaque paste or putty, and can then be digitally applied directly or by injection into the defect site.

WELLGRAFT PE I Resorbable Bone Void Filler is osteoconductive which acts as a scaffold and facilitate new bone growth. After implanted, it will be resorbed in approximately 60~90 days and be replaced by new bone during the healing process. This product is supplied sterile for single patient use.

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6. Intended Use: **WELLGRAFT PE I Resorbable Bone Void Filler** is indicated to fill bony void or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects created from traumatic injury to the bone. The bone void filler resorbs and is replaced with new bone during the healing process. **WELLGRAFT PE I** may be used at an infected site. When used in the spine, the device is limited to posterolateral fusion procedures only.

7. Performance Summary: The device conforms to applicable standards includes ISO 10993 series : Biological evaluation of medical devices , ASTM F2224-03 : Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants & ANSVAAMI/ISO 11137 Sterilization of Health Care Products - Radiation Sterilization

----etc.

8. Conclusions:

The **WELLGRAFT PE I Resorbable Bone Void Filler** has the same intended use and similar technological characteristics as the **OSTEO-G BONE VOID FILLER SYSTEM (K031319)** marketed by **ASPINE USA, INC.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **WELLGRAFT PE I Resorbable Bone Void Filler** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GWOWEI Technology Co., Ltd.
% Harvest Consulting Corporation
Ms. Jennifer Reich
2904 N. Boldt Drive
Flagstaff, AZ 86001

APR - 4 2008

Re: K072444
Trade/Device Name: Wellgraft PE I Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: April 2, 2008
Received: April 3, 2008

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K#072444

Device Name: **WELLGRAFT PE I Resorbable Bone Void Filler**
GWOWEI Technology CO., LTD.

Indications for Use:

WELLGRAFT PE I Resorbable Bone Void Filler is indicated to fill bony void or gaps of the skeletal system (i.e., the extremities, spine and pelvis) that are not intrinsic to the stability of the bone structure. These defects may be surgically created osseous defects created from traumatic injury to the bone. The bone void filler resorbs and is replaced with new bone during the healing process. Wellgraft PE I may be used at an infected site. When used in the spine, the device is limited to posterolateral fusion procedures only.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark R Ogden for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072444